UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

James E. McLeod and Glenda McLeod, Plaintiffs, v. Sandoz, Inc., Defendant.	)	Civil Action No.: 4:16-CV-01640-RBH **ORDER**

This matter is before the Court on Defendant Sandoz, Inc.'s [ECF No. 24] motion to dismiss the amended complaint. For the reasons stated below, the Court grants Defendant Sandoz, Inc.'s motion to dismiss.[1]

Background

This case arises from Plaintiff James E. McLeod's use of the pharmaceutical drug amiodarone for treatment of his non-life threatening atrial fibrillation. Plaintiffs allege that after ingesting amiodarone, which was manufactured by Defendant Sandoz, Inc. ("Sandoz"), McLeod developed and was diagnosed with shortness of breath and chronic obstructive and progressive pulmonary disease. [Amended Complaint, ECF No. 23, at ¶ 18]. The amiodarone tablets were manufactured and sold by Sandoz as a generic version of Wyeth's Cordarone®.

Plaintiffs generally allege that Sandoz failed to adequately warn Plaintiff of the risks associated with the off-label use of amiodarone to treat non-life threatening atrial fibrillation, particularly the risk of pulmonary toxicity-lung disease. Plaintiffs contend Sandoz failed to

[1] Under Local Civil Rule 7.08 (D.S.C.), "hearings on motions may be ordered by the Court in its discretion. Unless so ordered, motions may be determined without a hearing." Upon review of the briefs, the Court finds that a hearing is not necessary.

adequately warn when it failed to provide a Medication Guide with Plaintiff's prescription. Plaintiffs allege the risks of amiodarone were disclosed in the Medication Guide and had the Plaintiff received the Medication Guide, he would have been aware of the serious lung related side effects and would not have taken amiodarone. *Id*. at ¶¶ 38-39. Plaintiffs also generally allege that Sandoz fraudulently marketed amiodarone for the off-label use of treating non-life threatening atrial fibrillation.

Plaintiffs filed their Complaint on May 23, 2016, alleging claims against Defendant Sandoz, Inc. for: 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; 4) negligence *per se* - "off label" marketing/sale and failure to provide Medication Guide; 5) fraud and deceit; and 6) loss of consortium.

In an Order dated March 31, 2017, the Court dismissed Plaintiffs' claims for 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; and 4) negligence *per se* - "off label" marketing/sale and failure to provide Medication Guide. *See* [Order, ECF No. 21]. Specifically, the Court held that Plaintiffs' failure to warn claims based on the failure to provide a Medication Guide were impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and 21 U.S.C. § 337(a) because the requirement to provide a Medication Guide to distributors is based solely on the requirements of the FDCA and related regulations, and there is no parallel duty to provide a Medication Guide under South Carolina law. In a footnote, the Court noted that Plaintiff's claims relating to the failure to provide a Medication Guide were also due to be dismissed because, pursuant to the learned intermediary doctrine, the manufacturer's duty to warn extended only to the prescribing physicians, not the patient. The Court also held that Plaintiffs' negligent "off-label" promotion claim was

impliedly preempted under *Buckman*.

The only claims that were not dismissed were Plaintiffs' fraudulent off-label marketing claim and the loss of consortium claim. However, as to the fraudulent off-label marketing claim, the Court found that the original Complaint failed set forth facts sufficient to establish causation in light of the learned intermediary doctrine because: 1) Plaintiffs had not alleged that Plaintiff's prescribing physicians were unaware of the warnings set forth in the Medication Guide or the risk of pulmonary toxicity or lung problems possibly resulting in death; and 2) Plaintiffs had not alleged that the prescribing physicians would have changed their decision to prescribe amiodarone had they been aware of the risk of pulmonary toxicity or lung problems resulting in death. The Court permitted Plaintiffs to amend their fraudulent off-label marketing claim to state facts sufficient to establish causation under the learned intermediary doctrine. The Court also advised Plaintiffs that any amendment to their fraudulent off-label marketing claim must comply with the specificity requirements for fraud claims under Rule 9(b) of the Federal Rules of Civil Procedure.

On April 14, 2017, Plaintiffs filed an Amended Complaint alleging claims for fraudulent off-label marketing and loss of consortium. [Amended Complaint, ECF No. 23]. In response, Sandoz filed a second motion to dismiss arguing that Plaintiffs disregarded the Court's directives and filed an Amended Complaint that contained many of the same deficiencies as the first complaint. Sandoz argues that Plaintiffs' Amended Complaint fails to establish causation under the learned intermediary doctrine. Sandoz also argues the Amended Complaint fails to meet the particularity requirements for fraud claims under Rule 9(b) of the Federal Rules of Civil Procedure. Sandoz further argues that Plaintiffs' Amended Complaint contains reworded claims that the Court clearly dismissed with prejudice.

Even though Plaintiffs' Amended Complaint attempts to resurrect claims that were already dismissed with prejudice, the only claims properly before this Court at this time are Plaintiffs' fraudulent off-label marketing claim and the loss of consortium claim.

In their fraudulent off-label marketing claim, Plaintiffs allege that Sandoz owed a duty to provide honest, accurate, and complete information to Plaintiff, his physicians, and the public. [Amended Complaint, ECF No. 23 at ¶ 89]. Plaintiffs allege that Sandoz misled and deceived Plaintiff, his physicians, and the public into believing that amiodarone was safe and effective for use in the treatment of atrial fibrillation. *Id*. at ¶ 90. Sandoz allegedly concealed and understated the health hazards and risks associated with the "off-label" use of amiodarone to treat non-life threatening atrial fibrillation. *Id*. at 92. Sandoz allegedly failed to fully inform Plaintiffs' physicians of the true defects in amiodarone. *Id*. at ¶ 95.

Plaintiffs allege Sandoz concealed material facts they were obligated to disclose, including that amiodarone was not FDA approved for the treatment of atrial fibrillation, was not an appropriate "first line of treatment" for atrial fibrillation, is required to be accompanied by a Medication Guide intended to warn the consumer of the serious, life-threatening complications from the use of amiodarone, and was approved by the FDA only for limited use without any associated clinical trials. *Id*. at ¶ 99. Plaintiffs allege Sandoz engaged other medical professionals to deceptively promote the off-label use and purposely avoided detailed discussions of adverse reactions related to lung and vision injuries. *Id*. at ¶ 100. Plaintiffs allege the prescribing physicians justifiably and reasonably relied to their detriment on Sandoz's misrepresentations and omissions and their reliance on those misrepresentations and omissions proximately caused Plaintiff's injuries. *Id*. at ¶ 101.

Rule 12(b)(6) Standard

When deciding a motion to dismiss made under Federal Rule of Civil Procedure 12(b)(6), the Court must accept all well-pled facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009). A complaint must state a "plausible claim for relief" to survive a 12(b)(6) motion to dismiss. *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The Court will not dismiss the plaintiff's complaint so long as he provides adequate detail about his claims to show he has a "more-than-conceivable chance of success on the merits." *Owens v. Baltimore City State's Attorneys Office*, 767 F.3d 379, 396 (4th Cir. 2014) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 563. A complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570. However, when a plaintiff's assertions "amount to nothing more than a 'formulaic recitation of the elements' " of a cause of action, the Court may deem such allegations conclusory and not entitled to an assumption of veracity. *Iqbal*, 556 U.S. at 681 (quoting Twombly, 550 U.S. at 555).

Discussion

Sandoz argues that Plaintiffs disregarded the Court's directives and filed an Amended Complaint that simply contains reworded claims that the Court already dismissed with prejudice. The first page of Plaintiffs' response brief indicates that Sandoz is correct. Inexplicably, Plaintiffs state "James McLeod's amended complaint again alleges common-law negligent failure to warn claims based on Sandoz's failure to provide the FDA required Medication Guide to James."

[Plaintiff's Response in Opposition to Sandoz's Motion to Dismiss the Amended Complaint, ECF No. 25 at 1]. Plaintiffs' common law negligence claim based on Sandoz's failure to provide a Medication Guide was dismissed as impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and 21 U.S.C. § 337(a) because the requirement to provide a Medication Guide to distributors is based solely on the requirements of the FDCA and related regulations, and there is no parallel duty to provide a Medication Guide under South Carolina law. Additionally, under South Carolina law and the learned intermediary doctrine, the manufacturer's duty to warn extends only to the prescribing physician, not the patient. *See Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir.1992); *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 504 (D.S.C. 2012).

To the extent Plaintiffs attempt to re-allege failure to warn claims based on Sandoz's failure to provide a Medication Guide, those claims have already been dismissed with prejudice and are not properly before this Court.

The only claims properly before the Court at this stage are Plaintiffs' fraudulent off-label marketing claim and the loss of consortium claim based on the alleged fraudulent off-label marketing. In the March 31, 2017 Order, the Court found that Plaintiffs' fraudulent off-label marketing claim failed to state a plausible claim because it did not contain facts sufficient to establish causation in light of the learned intermediary doctrine. The Court then permitted Plaintiffs to file an Amended Complaint to cure the causation defect with Plaintiffs' fraudulent off-label marketing claim.

The question now is whether Plaintiffs' Amended Complaint states facts sufficient to establish causation under the learned intermediary doctrine. Under the learned intermediary

doctrine, “the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device.” *Odom*, 979 F.2d at 1003. The manufacturer of a drug has a duty to warn the patient’s doctor who acts as a “learned intermediary” between the patient and the manufacturer. In a prescription drug case, a plaintiff must not only show that the drug manufacturer's warning was inadequate, but “also establish that the inadequacy of the warning was the proximate cause of the plaintiff's injury.” *Sauls*, 846 F. Supp. 2d at 502 (citing *Stanback v. Parke, Davis, & Co.*, 657 F.2d 642, 645 (4th Cir.1981)). In light of the learned intermediary doctrine, “the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.” *Odom*, 979 F.2d at 1003.

Plaintiffs again have failed to state facts sufficient to establish causation under the learned intermediary doctrine. Plaintiffs' response in opposition to Sandoz's motion to dismiss the Amended Complaint does not even address the learned intermediary doctrine and appears to focus on the already dismissed claims based on Sandoz's alleged failure to provide a Medication Guide.

Plaintiffs' Amended Complaint alleges "[t]he most serious side effect of amiodarone and the one requiring the patient Medication Guide is pulmonary toxicity-lung disease." [Amended Complaint, ECF No. 23 at ¶ 83]. Plaintiffs contend that the prescribing physicians were misled regarding the safety and efficacy of amiodarone for the off-label use of treating non-life threatening atrial fibrillation but Plaintiffs do not allege that the prescribing physicians were unaware of the

"most serious side effect."[2] Like the original Complaint, the Amended Complaint does not allege that Plaintiff's prescribing physicians were unaware that pulmonary toxicity-lung disease was a side effect of amiodarone. The Amended Complaint does not allege that Plaintiff's prescribing physicians would have changed their decision to prescribe amiodarone had they been aware of the risk of pulmonary toxicity-lung disease. Accordingly, Plaintiffs have failed to state a claim to relief that is plausible on its face as Plaintiffs have not pled facts sufficient to establish causation in light of the learned intermediary doctrine.[3] *See, e.g. Luberda ex rel. Luberda v. Purdue Frederick Corp.*, No. 4:13-cv-00897-RBH, 2014 WL 1315558, at *6 (D.S.C. March 28, 2014).

Upon further consideration, the Court also finds that Plaintiffs' fraudulent "off-label" marketing claim would be preempted under *PLIVA Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466, 2470, 186 L.Ed.2d 607 (2013) for the reasons stated in *Bean v. Upsher-Smith Pharms., Inc.*, No.: 4:16-cv-01696-RBH, 2017 WL 4348330, at *4-6 (D.S.C. Sept. 29, 2017).[4]

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[2] The Court anticipates Plaintiffs would have a problem securing testimony from the prescribing physicians that they were unaware of the most serious side effect of a drug they were actively prescribing, especially when that side effect was disclosed in a Medication Guide. Such a lack of awareness on the part of the prescribing physician could arguably amount to medical malpractice.

[3] The Fourth Circuit has applied the learned intermediary doctrine to a fraud case brought under Virginia law. This Court predicts that South Carolina courts would also apply the doctrine in a fraud case regarding prescription drugs involving misbranding or the failure to warn. *See Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999).

[4] In *Mensing*, the plaintiffs alleged that they were injured after consuming generic metoclopramide and asserted an array of state law claims against the generic product's manufacturers, including strict liability failure to warn, negligent failure to warn, breach of express and implied warranties, misrepresentation, fraud, unfair trade practices, false advertising, and consumer fraud. The Supreme Court held that all state law tort claims involving generic drugs that impose a duty to change a drug's label are preempted by federal law. *Mensing*, 564 U.S. at 609.

Mensing and *Bartlett* establish that under the FDCA a generic drug manufacturer, such as Sandoz, may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability for its failure to change its labeling, design, or formulation. *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014).

Within their response to the motion to dismiss, Plaintiffs request leave to amend the complaint a second time. Rule 15(a)(2) of the Federal Rules of Civil Procedure directs that leave to amend "shall be freely given when justice so requires." Leave to amend a pleading should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile. *See Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th Cir. 1986). In this case, Plaintiffs do not elaborate as to what amendments they would make to the Amended Complaint but instead generally request leave to amend. Leave to amend is properly denied where the requested leave to amend is not accompanied by a motion to amend or a proposed amended complaint. *See Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 630-31 (4th Cir. 2008) (finding no abuse of discretion where plaintiffs requested leave to amend in a response but did not file a motion to amend or a proposed amended complaint). Accordingly, in the absence of a motion to amend accompanied by a proposed Second Amended Complaint, Plaintiffs' request to amend is denied. Furthermore, as discussed above, Plaintiffs'

In *Drager*, the Fourth Circuit found plaintiff's state law claims for negligent marketing, strict liability, breach of express and implied warranty, negligent misrepresentation, and fraudulent concealment were preempted by the FDCA. 741 F.3d 470. Specifically, the plaintiff in *Drager* alleged that PLIVA made negligent misrepresentations and fraudulently concealed information about the safety of its product from consumers and medical professionals. *Id*. at 479. Finding preemption, the Fourth Circuit stated "[a]ssuming that PLIVA's representations are false and misleading because its metoclopramide is unreasonably unsafe as marketed, it has no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or truthful. *Id*. PLIVA's only remaining options were to leave the market or accept tort liability. *Id*. As a result, the Fourth Circuit found plaintiff's misrepresentation and fraudulent concealment claims were preempted by the FDCA. *Id*.

In this case, the basis for Plaintiff's "off-label" marketing claim is that Sandoz, by virtue of its marketing of amiodarone for first line non-life threatening atrial fibrillation treatment instead of "last resort" treatment, rendered the manufacturer's warning inadequate. Under the FDCA and FDA regulations, Sandoz could not add or strengthen any warnings for amiodarone to address any risks associated with off-label use. If successful, Plaintiff's "off-label" promotion claims would necessarily require Sandoz to either: 1) change the warning label or disseminate additional warnings to reflect the alleged additional dangers associated with the "off-label" use of amiodarone for atrial fibrillation; 2) accept state tort liability; or 3) exit the market place. As with the claims in *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014), such a result requires preemption under *Mensing* and *Bartlett*. Plaintiffs' fraudulent "off-label" promotion claim is preempted by the FDCA.

fraudulent "off-label" marketing claim is preempted by federal law. Any proposed amendment to the complaint would most likely be futile.

Plaintiffs' loss of consortium claim, which is derivative and premised solely on dismissed and preempted claims, is also dismissed.

Conclusion

For the reasons stated above, Defendant Sandoz, Inc.'s [ECF No. 24] motion to dismiss the Amended Complaint is **GRANTED.** This case is **DISMISSED with prejudice**.

IT IS SO ORDERED.

March 23, 2018
Florence, South Carolina

s/ R. Bryan Harwell
R. Bryan Harwell
United States District Judge